**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF NEW YORK**

| | |
|---|---|
| BRECKENRIDGE PHARMACEUTICAL, INC., Plaintiff, v. MIDLAND HEALTHCARE, LLC, Defendant. | Civil Action No. 07-CV-11114(RWS) NOTICE OF MOTION |

**NOTICE OF MOTION FOR SUMMARY JUDGMENT**
**OF BRECKENRIDGE PHARMACEUTICAL, INC.**

PLEASE TAKE NOTICE that upon the annexed declaration of Larry J. Lapila, executed January 30, 2008, and the exhibits thereto, and the annexed declaration of Robert Falconer, also executed January 30, 2008, Plaintiff Breckenridge Pharmaceutical, Inc. ("Breckenridge") through counsel, on the 13th day of February, 2008, or as soon thereafter as counsel may be heard, will move this Court before the Honorable Robert W. Sweet at the United States Courthouse for the Southern District of New York, 500 Pearl Street, New York, New York, for an Order granting summary judgment pursuant to Fed. R. Civ. P. 56 on Breckenridge's claim against Defendant Midland Healthcare, LLC.

Dated: New York, New York
January 30, 2008

/s/ C. Randolph Ross

C. Randolph Ross, Esquire (CR 8966)
Timothy J. Fierst, Esquire (TF 3247)
CROWELL & MORING, LLP
153 East 53rd Street, 31st Floor
New York, New York 10022
Telephone: (212) 895-4200
Fax: (212) 223-4134

Kristi A. Davidson, Esquire (KD 4753)
BUCHANAN INGERSOLL & ROONEY PC
One Chase Manhattan Plaza, 35th Floor
New York, NY 10005-1417
Telephone: (212) 440-4400
Fax: (212) 440-4401

*Attorneys for Plaintiff*

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF NEW YORK**

| | | |
|---|---|---|
| BRECKENRIDGE PHARMACEUTICAL, INC., | ) | |
| Plaintiff, | ) | |
| v. | ) | Civil Action No. 07-CV-11114(RWS) |
| MIDLAND HEALTHCARE, LLC, | ) | |
| Defendant. | ) | JURY TRIAL DEMANDED |

**DECLARATION OF LARRY J. LAPILA IN SUPPORT OF THE MOTION OF BRECKENRIDGE PHARMACEUTICAL, INC. FOR SUMMARY JUDGMENT**

LARRY J. LAPILA declares, under penalty of perjury, that the following is true and correct:

1. I am the Vice President of Business Development for Plaintiff Breckenridge Pharmaceutical, Inc. ("Breckenridge"), where I have been employed since 2001. I have been engaged in the development, marketing, and sales of pharmaceutical products for more than 25 years, and am familiar with the relevant practices and terminology in the pharmaceutical industry.

2. In part because of my recommendation to my business colleagues at Breckenridge, on January 26, 2007, Breckenridge entered into an ANDA Development, Manufacture, and Supply Agreement (the "Agreement") with Defendant Midland Healthcare, LLC ("Midland"), relevant portions of which are filed herewith as Exhibit 1.[1]

3. The Agreement provides that Breckenridge was to pay Midland a certain total

[1] Because of the confidential nature of the Agreement, only the pertinent pages (redacted) are submitted herewith. If necessary, a full copy will be filed under seal at an appropriate time, upon approval of the requisite motion.

sum for the development of a prescription product (the "Product") to the point at which Breckenridge could submit an Abbreviated New Drug Application ("ANDA") for approval by the United States Food and Drug Administration ("FDA") so that the Product could be marketed in the United States, with certain amounts due to Midland only upon FDA approval. *See* Agreement (Exh. 1), at section 2.1 and Exhibit B thereto.

4. The services to be rendered by Midland are defined by the Agreement as "the development of the Product for submission of an ANDA," which included such specific development services as "formulation development, pilot-scale and scale-up batch manufacturing, analytical method development, method validation, and stability testing for the Product." Agreement (Exh. 1), section 2.1(a) and (b).

5. In Exhibit B to the Agreement, these services were broken down into certain "milestones." *Id.*, Exhibit B thereto.

6. Exhibit B also provides that certain specified payments were to be made by Breckenridge to Midland upon the achievement of these "milestones." *Id.*

7. The second milestone in the Agreement is the "completion of formulation development," which was to be achieved 120 days after the execution of the Agreement. *Id.*

8. In the months leading up to September, 2007, Midland advised Breckenridge that stability testing was being performed on a development batch of the Product, and that appropriate progress was being made on the subsequent milestones. In spite of its contractual obligation to provide accurate monthly status reports, Midland failed to advise Breckenridge that in fact the formulation development had not been completed.

9. Based on Midland's representations, Breckenridge paid to Midland a total of $200,000.

10. The Agreement defines "completion of formulation development" to include "comparative assay results for the pilot-scale batch, and successful completion of analytical method validation, including impurities." Agreement (Exh. 1), section 1.7.

11. In addition, one of the standard steps required for formulation development of a pharmaceutical product is stability testing on product that has been produced pursuant to the formulation.

12. It is a customary practice in the pharmaceutical industry to conduct on-site audits of contractors such as Midland. In September, 2007, on behalf of Breckenridge, I and a regulatory consultant, Robert Falconer, conducted such an on-site audit of Midland's progress.

13. During this audit we discovered that, contrary to Midland's earlier representations, Midland had not produced a pilot-scale batch, had not produced comparative assay results, had not completed analytical method validation, and had not performed (or even begun to perform) stability testing of the formulation.

14. To this date, Midland has still not rendered any of the services specified in section 2.1 of the Agreement, and none of the milestones specified in Exhibit B to the Agreement except for "Execution of Agreement." *See* Exhibit B to the Agreement (Exh. 1).

15. On September 26, 2007, I personally emailed Mr. Raman ("Ray") Kapur of Midland that we had learned from our site visit that stability testing had not been performed on a development batch as Midland had previously represented, and that the Product development was off schedule. *See* Exhibit 2 (09/26/2007 email to Midland).

16. Because Breckenridge had entered into this project with Midland based on my own recommendation, I subsequently emailed to Mr. Kapur, on November 12, 2007: "You have put me in a VERY embarrassing position. . . . This project has died due to Midland's failure to

get it up on stability in a timely manner. Since our visit I have found it impossible to get information from you." *See* Exhibit 3 (11/12/2007 to 11/19/2007 emails between Midland and Breckenridge).

17. I also asked for the return of the money that had been paid by Breckenridge to Midland, but Midland has not returned any of the amount paid to it. *See* Exhibit 3.

18. Mr. Kapur's reply emails to me did not contradict my assertions that the project had "died due to Midland's failure to get it up on stability in a timely manner," nor did Mr. Kapur disagree with my other assertions, but instead effectively admitted them. *See* Exhibit 3.

19. Thus, rather than disagree with my statement of the facts, Mr. Kapur instead apologized twice for putting me in this position. He also requested time to complete a "restructuring transaction," and stated that he would come back to me "with a proposal," and was "looking into a couple of other things . . . to see what else we can do together." Exh. 3.

20. Midland also failed to provide to Breckenridge at least two consecutive monthly reports that were required by the section 2.3 of the Agreement, and failed to provide other reports requested by Breckenridge as well. *See* Agreement (Exh. 1), at section 2.3.

21. In spite of the fact that Midland had not achieved any of the milestones after execution of the Agreement, Midland has not returned any of the money paid to it by Breckenridge for the development of the Product.

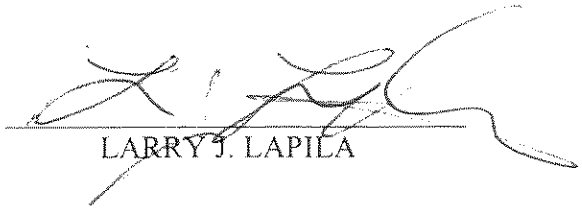
22. In light of Midland's failures to achieve the milestones and to provide the requisite reports, on November 30, 2007, Breckenridge sent to Midland a letter terminating the Agreement pursuant to section 7.2 of the Agreement. *See* Exhibit 4.

23. Midland has not rendered any of the services to be provided to Breckenridge pursuant to section 2.1 of the Agreement or Exhibit B thereto, so that there have been no "actual

services rendered" by Midland that were to be provided to Breckenridge pursuant to the Agreement.

I declare under penalty of perjury, that the foregoing is true and correct.

Executed at New Berlin, Connecticut on January 30, 2008.



LARRY J. LAPILA

# ANDA DEVELOPMENT, MANUACTURE, AND SUPPLY AGREEMENT

ANDA [redacted] (generic of [redacted])

THIS AGREEMENT entered into as of this 26th day of January, 2007 by and between BRECKENRIDGE PHARMACEUTICAL, INC., a Florida corporation with a principal place of business at 1141 S. Rogers Circle, Suite 3, Boca Raton, FL 33487 ("Breckenridge") and MIDLAND HEALTHCARE LLC, 1201 Douglas Avenue, Kansas City, KS 66103 (hereinafter referred to as "Midland") (hereinafter collectively the "Parties").

WHEREAS, Breckenridge is engaged in the business of developing, marketing and selling pharmaceutical drug Product;

WHEREAS, Midland is engaged in the business of developing, manufacturing, and supplying pharmaceutical drug Product;

WHEREAS, Midland desires to provide to Breckenridge and Breckenridge wishes to obtain certain product development services in connection with the submission and sponsorsh ip of an ANDA for [redacted], and, upon FDA approval, which will be contract manufactured exclusively by Midland for and sold exclusively by Breckenridge;

NOW, THEREFORE, for the consideration and covenants set forth herein, the receipt and sufficiency of which are hereby acknowledged, the parties hereby agree as follows:

## *SECTION 1: DEFINITIONS*

1.1 ANDA. The acronym, Abbreviated New Drug Application, as defined in section 505(j) of the Federal Food Drug & Cosmetic Act, as amended.

1.2 ANDA Approval. The date on which Breckenridge receives either the approval letter, or tentative approval letter, from the FDA that the Product submitted meets applicable standards required for ANDA's.

1.3. ANDA Filing. The date on which Breckenridge receives the letter from the FDA confirming acceptance of the ANDA submission.

1.4 Affiliate. Any corporation or other legal entity whereby fifty percent (50%) or more of its voting capital shares or similar voting securities is owned by one of the Parties.

1.5 API. The acronym, active pharmaceutical ingredient.

1.6 Completion of Biostudies. If required as part of the ANDA submission, the date of receipt of a final report relating to an FDA-compliant clinical bioequivalence study (with protocol approved by the Office of Generic Drugs, if applicable) utilizing a completed Exhibit Batch and predetermined acceptance criteria.

1.7 Completion of Formulation Development. The successful manufacture of a pilot-scale batch, receipt by Breckenridge of acceptable comparative assay results for the pilot-scale batch, and successful completion of analytical method validation , including impurities.

1.8 Completion of Scale-Up. The successful manufacture of the ANDA Exhibit Batch and receipt by Breckenridge of acceptable comparative assay results.

1.9 FDA. The United States Food and Drug Administration.

1.10 Milestones. The specific events and timelines identified by Breckenridge and agreed to by Midland within the scope of Services performed by Midland pursuant to this Agreement and referenced in Exhibit B.

1.11 Product. The finished-dosage form referenced in Exhibit A which Midland has agreed to develop and manufacture as part of its Services for Breckenridge.

1.12 Project Commencement Date. The date upon which the last party executes this Agreement.

1.13 Services. Those services related to the development of the Product for ANDA submission, which Midland shall provide to Breckenridge pursuant to this Agreement, referenced in Exhibit A.

1.14 ANDA Exhibit Batch. The production of no less than [redacted]% of the commercial quantity of the Product, which meets all required quality assurance and quality control specifications, measured by sufficient manufacturing and release testing of exhibit batches, as per pre-approved specifications mutually acceptable to the Parties.

## *SECTION 2: PRODUCT DEVELOPMENT SERVICES*

2.1 Product Development. Midland shall develop the Product according to the Services referenced in Exhibit A and the milestones and related timelines in Exhibits B. Breckenridge, as sponsor, shall submit the ANDA's in its name. In summary:

(a) Midland shall be wholly responsible for the development of the Product for submission as an ANDA;

(b) Midland shall be wholly responsible for and perform formulation development, pilot-scale and scale-up batch manufacturing, analytical method development, method validation, and stability testing for the Product on site at its facility, in addition to determining whether bioequivalence studies are necessary for ANDA submission (and, if so, assist in preparation for) and assisting Breckenridge in all regulatory filing activities for the Product;

(c) Midland shall be responsible to obtain [redacted]

(d) Midland shall be wholly responsible for the management and supervision of the Services in connection with the submission and prosecution of the ANDA, including, without limitation, ANDA document preparation, review and submission, miscellaneous administrative and regulatory support, and any other assistance to Breckenridge in its submission of the ANDA.

2.2. Ownership and Assignment of Property Rights. Breckenridge shall be the sole owner of all rights, title, and interest in the ANDA, which includes any inventions, patentable technology, patent applications, patents, trade secrets, and technical know-how relating to techniques and processes that are specific only to the [redacted] product, which will be utilized to develop the Product for Breckenridge, and, for any processes that are generally related to the production and development of [redacted] such as common analytical, testing, and assay procedures and methods, and to the extent such rights are not owned by Breckenridge, an unconditional, perpetual, non-exclusive and royalty free license to all such intellectual property and physical work developed before, during and relating to Services performed under this Agreement, ("Breckenridge IP"). Nothing contained herein is intended to restrict or limit in any manner Midland's rights including the rights to develop and own the technology to produce products and ANDAs, including products containin[redacted] other than the Product. Breckenridge shall not sell, assign, or transfer the ANDA to any third party without first obtaining the consent of Midland, which shall not be unreasonably withheld, so long as the terms of such sale and the party to whom it is sold remain commercially reasonable for Midland so that it is not in any commercially worse position than in the present Agreement.

2.3. Status Meetings and Reports. Midland shall submit to Breckenridge, within ten (10) days after the last day of each month that this Agreement is in effect, monthly reports describing the progress of the development of the Product, reasonably acceptable to Breckenridge. The failure of Midland to provide two (2) consecutive monthly reports in a timely manner shall be a breach giving Breckenridge a right to (i) suspend its performance under this Agreement, or, after notice by Breckenridge, (ii) terminate this Agreement in accordance with the termination provisions of this Agreement. In addition to the monthly reports, Midland shall provide any other reports reasonably requested by Breckenridge relating to the completion and/or attempted completion of the Milestones or related timelines. If reasonably requested by one party, the other party shall agree, in good faith, to engage in discussions and/or meetings to review and discuss the progress of the Milestones and any other issues to be determined by the Parties.

2.4. Costs for Development Services. In consideration for the successful completion of the Services to be performed by Midland, Breckenridge shall pay Midland pursuant to the milestones and timelines referenced in Exhibit B. In sum, Breckenridge shall pay Midland $[redacted] for its development services, [redacted] See Exhibit B. In the event Midland is unable to complete the Services hereunder, Breckenridge may terminate this Agreement in accordance with Section 7.2(b), Exhibit C.

***SECTION 3: MANUFACTURE AND SUPPLY***

3.1. Manufacture of Product. The parties understand and agree that the obligations hereunder to manufacture, supply, and purchase the Product are contingent upon FDA Approval of the Product.

for conduct relating to the regulation of any product under the Federal Food, Drug and Cosmetic Act. Midland shall provide for FDA submission a standard "Debarment Certification" upon request of Breckenridge.

(d) Breckenridge has a sales operation that reaches all trade segments for generic products. Breckenridge will use its commercially reasonable efforts to sell the Product that are no less than what it would employ with other products in its line of similar value. [redacted]

5.3. Insurance.

(a) Midland represents and warrants that it has obtained and shall at all times during the term of this Agreement maintain at its own cost and expense, in respect to its performance hereunder: (i) worker's compensation insurance in accordance with the statutory requirements of Kansas; (ii) product liability insurance with a minimum of [redacted] combined single limit for bodily injury and property damage per occurrence, and which includes Breckenridge as an additional insured ; and (iii) upon delivery to Breckenridge, physical property damage insurance, through the designated freight carrier or otherwise, on all of the Product at all times until receipt by Breckenridge . If requested by Breckenridge, Midland will supply its certificate of insurance to evidence such coverage.

(b) Breckenridge represents and warrants that it has obtained and shall at all times maintain at its own cost and expense in respect to its performance hereunder product liability insurance with respect to the Product with minimum coverage of [redacted] per occurrence. Breckenridge will supply Midland with a certificate of insurance to evidence such coverage, upon request.

## SECTION 6. CONFIDENTIALITY

The Parties refer to the Mutual Confidentiality Agreement previously executed between the Parties, which is expressly incorporated herein.

## SECTION 7. TERM AND TERMINATION OF AGREEMENT

7.1 Term. The initial term of this Agreement shall be [redacted] from the date hereof. The Term shall be automatically extended for intervals of [redacted] unless either party provides written notice at [redacted] prior to expiration of the then current term. [redacted]

7.2 Termination.

(a) Breckenridge and Midland mutually agree that the Services performed under this Agreement will be measured by the accomplishment of certain Milestones as set forth in Exhibit B.

(b) Breckenridge may terminate this Agreement for Midland's breach of its material obligations hereunder; material breach is defined to include (i) failure to accomplish certain Milestones in accordance with Exhibit B, (ii) provide reports in accordance with Section 2.3, or comply with audits and inspections or provision of documents in accordance with Section 3.4, or (iii) or material breach of any representations or warranties contained herein, at any time by giving at least sixty (60) days' prior written notice of termination to Midland, and so long as Midland fails to remedy the breach to the reasonable satisfaction of Breckenridge prior to the expiration of the sixty (60) day notice period provided the breach is capable of being cured within the 60 day period.

If Breckenridge exercises its option to terminate this Agreement in accordance with the provisions of this Section 7.2(b), Breckenridge's obligations to pay for development services shall cease upon completion of the notice period, if applicable, and Midland will prepare a reconciliatory billing for actual services rendered. This billing will represent actual time and costs reasonably incurred by Midland on the project through the date of termination. The billing will be deducted from (or added to, as the case may be) the payments made to date pursuant to Exhibit B, and the balance owed by (or due to) either party will be paid in full within thirty (30) days after the receipt of the Midland reconciliatory billing invoice.

IN WITNESS WHEREOF, each of Breckenridge and Midland have executed this Agreement by their duly authorized officers as of the date first set forth above.

| MIDLAND HEALTHCARE LLC | BRECKENRIDGE PHARMACEUTICAL, INC. |
|---|---|
| By: | By: |
| Name: Ramun Kapur | Name: Larry J. Lapila |
| Position: Chairman | Position: Vice President Business Development |
| Dated: January 26, 2007 | Dated: January 26, 2007 |

**EXHIBIT A** — ***Services***

| | |
|---|---|
| **PRODUCT** | ANDA for [redacted] (generic of [redacted]) |
| **INITIAL FULLY-ABSORBED TRANSFER COST** (price of [redacted] Midland) | [redacted] *see below |
| **BATCH SIZE** | [redacted] (equivalent to [redacted]) |

Midland agrees to use commercially reasonable efforts (i) to provide product development services to Breckenridge, (ii) to support Breckenridge in the submission and sponsorship of the ANDA for FDA approval, for which Breckenridge shall be the sponsor of the ANDA, and (iii) to assist in the launch of the Product as required by Breckenridge. Midland's obligations and responsibilities include, but are not limited to, the following:

- To develop the Product from concept through final product formulation, including engineer and develop formulations, manufacturing processes, methods, in-process controls, and validate all methods regarding the Product in accordance with USP
- To audit raw material manufacturer, if mutually-agreed upon by parties
- To development all documentation for the manufacture of pilot and ANDA exhibit stability batches
- To manufacture and package the pilot and exhibit stability batches and place on stability
- To assist as necessary in the filing and prosection of the ANDA for the Product, including without limitation the preparation of all sections related to work performed by Midland
- To assist as needed with all responses to all FDA questions concerning Product submission
- To be available for all FDA inspections if necessary relevant to the developed Product until Product launch
- To perform all necessary regulatory research concerning the approval of the ANDA
- To assist in the evaluation and selection of a CRO to perform necessary studies, if necessary
- To ensure that all Services performed comply with applicable FDA regulations, including, without limitation, cGMP standards
- To manage and supervise the projects, and provide all other reasonable clerical and regulatory support necessary to obtain approval of the ANDA

**EXHIBIT A** **Services**

**[redacted]ransfer Cost (initial) ***

Invoice cost of all Raw & Packaging Materials
Incoming Freight costs & customs clearance
Testing Costs – In house
Testing Costs – outside labs.
Direct Labor
Indirect Labor
Depreciation

Other Production Costs including utilities, maint

Allocated Overheads including QC/QA and ongoing costs of stability, Annual Reports etc.

- Laboratory
- Manufacturing incl Liability Ins, licenses
- Warehousing/Shipping
- Insurance

* Costs are preliminary and merely indicative. Costs may shift between categories. Will be finalized closer to launch.

***EXHIBIT B*** ***Payments Upon Milestone Achievement and Royalties***

**(1) MILESTONES:**

In consideration for the successful completion of the Services by Midland, Breckenridge shall pay Midland a flat fee of [redacted] inclusive of all fees, costs, and expenses ("Development Fee"). The Development Fee shall be paid in monthly installments in the amount of [redacted] for [redacted] consecutive months beginning in the month of contract execution, with [redacted] upon ANDA filing and acceptance and [redacted] upon FDA approval (including tentative) of the ANDA. The continuation of monthly payments by Breckenridge shall be contingent only upon Midland successfully completing each of the Milestones, as set forth below, subject to amendment upon mutual agreement by the parties:

| Milestone | TimeTables | Description | Individual Milestone Payment to Have Been Made to Midland | Cumulative Payments |
|---|---|---|---|---|
| 1 | Execution of Agreement | Project Commencement | [redacted] | [redacted] |
| 2 | 120 days from Project Commencement Date | Completion of Formulation Development | [redacted] | [redacted] |
| 3 | 180 days from Project Commencement Date | Completion of Scale-Up | [redacted] | [redacted] |
| 4 | 280 days from Project Commencement Date | Receipt by Breckenridge of satisfactory 3-month accelerated stability results for ANDA Exhibit Batch | [redacted] | [redacted] |
| 5 | 340 days from Project Commencement Date | ANDA Filing | [redacted] (Within 15 days of receipt of acceptance notice by FDA of the ANDA) | [redacted] |
| 6 | n/a | ANDA Approval | [redacted] (within 15 days of FDA approval or tentative approval of the ANDA) | [redacted] |

**From:** Larry J. Lapila [llapila@breckenridgepharma.com]
**Sent:** Wednesday, September 26, 2007 8:01 PM
**To:** Ray Kapur; Paul Sudhaker
**Cc:** **Gene Kim; **Judi-Lynn Reidinger; *Rob Falconer BPI
**Subject:** [redacted]evelopment

**Importance:** High

**Follow Up Flag:** Follow up
**Flag Status:** Flagged
Ray / Paul:

We were very disappointed to learn that [redacted]Development is off schedule
We had been advised that the product had stability from a development batch
We learned at our audit that this was not the case and it must now be set up
We also learned that you do not have final methods

Please confirm the status as of today and provide a Revised Time-Line

Also, thank you for the copy of the redacted 483
When can we expect a copy of your response?

Thanks

Larry J. Lapila
Vice President
Business Development

llapila@breckenridgepharma.com

Breckenridge Pharmaceutical, Inc.
15 Massirio Drive Suite 201
Berlin, CT 06037

Phone (860) 828-8140
Fax (860) 828-8142

**From:** Raman Kapur [ram.kapur@patmedia.net]
**Sent:** Monday, November 19, 2007 9:38 AM
**To:** llapila@bpirx.com
**Subject:** RE: [redacted]
Larry,
Our deal has been delayed by about 12 days. It will help me a great deal to come back to you after that. Meanwhile, I am also looking into a couple of other things including [redacted] to see what else we can do together. Sorry to put you in this position.
I will call you.

Ray

---

**From:** Larry Lapila [mailto:llapila@breckenridgepharma.com]
**Sent:** Friday, November 16, 2007 5:21 PM
**To:** Ray Kapur
**Subject:** [redacted]

I expected to hear something from you
Please call me Monday morning

---

**From:** Larry Lapila [mailto:llapila@breckenridgepharma.com]
**Sent:** Monday, November 12, 2007 11:14 AM
**To:** 'Raman Kapur'
**Cc:** 'Harvey Weintraub'
**Subject:** RE: [redacted]

Call me ASAP (860) 828 – 8140

Leave at 3PM and out until Friday

I need "something of value"

---

**From:** Raman Kapur [mailto:ram.kapur@patmedia.net]
**Sent:** Monday, November 12, 2007 11:11 AM
**To:** llapila@bpirx.com
**Cc:** 'Harvey Weintraub'
**Subject:** RE: [redacted]

Larry,

We are looking into the status of the [redacted] product.

Sorry for putting you in this position.

We had hoped to have completed our restrucutrring transaction by now and set our house in order.
That is still expected to occur wiithin the next 8 days.

Give us another 10 days and we will come back to you with a proposal.

Would greatly appreciate if you could work with us at a difficult time.

I will telephone you as well.

Thanks.

Ray

---

**From:** Larry Lapila [mailto:llapila@breckenridgepharma.com]
**Sent:** Monday, November 12, 2007 10:59 AM
**To:** Ray Kapur
**Cc:** Harvey Weintraub
**Subject:** FW: [redacted]
**Importance:** High

**Ray**

**You have put me in a VERY embarrassing position**

**What are we going to do?**

**I would like to get the money we have paid you back**

**This project has died due to Midland's failure to get it up on stability in a timely manor**
**Since our visit I have found it impossible to get information from you**

**I need an answer today**

**Larry**

---

Breckenridge Pharmaceutical, Inc.

November 30, 2007

***VIA OVERNIGHT DELIVERY AND ELECTRONIC MAIL***
***Email: ram.kapur@patmedia.net***

Paul Sudhakar
Vice Chairman
Midland HealthCare LLC
1201 Douglas Avenue
Kansas City, Kansas 66108

Raman Kapur
Chairman
Midland HealthCare LLC
791 Alexander Road
Princeton, New Jersey 08540

***Re: Notice of Termination***
***Midland-Breckenridge ANDA Development and Supply Agreement***
***Dated January 26, 2007 ("Agreement")***

Gentlemen:

In accordance with our numerous emails previously sent to Midland and discusssions during our September 12, 2007, meeting at your office, pursuant to Section 7.2 of the Agreement, Breckenridge hereby confirms the termination of the Agreement due to Midland's failure to timely comply with agreed-upon milestones and for failure to provide at least two (2) consecutive monthly reports and other reports requested by Breckenridge. Breckenridge will advise Midland shortly of its intentions concerning any post-termination rights and obligations as contained in the Agreement. Breckenridge reserves the right to claim additional events of breach against Midland, as well as other rights associated with this termination, whether or not contained in the Agreement.

Sincerely,

**Eugene L. Kim**
General Counsel

cc: Larry Runsdorf – President
Larry Lapila – Vice President, Business Development

Eugene L. Kim, General Counsel
Breckenridge Pharmaceutical, Inc., Connecticut Office, 15 Massirio Drive, Suite 201, Berlin, CT 06037
Phone: 860-828-8140 ○ Direct Fax: 860-760-6499 ○ Email: ekim@bpirx.com
www.breckenridgepharma.com

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE SOUTHERN DISTRICT OF NEW YORK**

| | | |
|---|---|---|
| BRECKENRIDGE PHARMACEUTICAL, INC., | ) | |
| Plaintiff, | ) | |
| v. | ) | Civil Action No. 07-CV-11114(RWS) |
| MIDLAND HEALTHCARE, LLC, | ) | |
| Defendant. | ) | |

**DECLARATION OF ROBERT A. FALCONER IN SUPPORT OF THE MOTION OF BRECKENRIDGE PHARMACEUTICAL, INC. FOR SUMMARY JUDGMENT**

ROBERT A. FALCONER declares, under penalty of perjury, that the following is true and correct:

1. I am a private consultant to the pharmaceutical industry, and currently devote much of my time to consulting work on behalf of Breckenridge Pharmaceutical, Inc. ("Breckenridge").

2. In September, 2007, I accompanied Mr. Larry Lapila of Breckenridge to the facilities of Midland Healthcare, LLC ("Midland") to carry out an on-site audit, which is standard industry practice.

3. This audit was in relation to a pharmaceutical product to be developed pursuant the ANDA Development, Manufacture, and Supply Agreement between Breckenridge and Midland, dated January 26th, 2007 (the "Product").

4. In the course of this audit, I ascertained that Midland had not produced a pilot-scale batch of the Product, had not produced comparative assay results, had not completed

analytical method validation, and had not performed (or even begun to perform) stability testing of the formulation for the Product.

I declare under penalty of perjury, that the foregoing is true and correct.

Executed at Richmond, Virginia on January 30, 2008.

/s/ Robert A. Falconer
ROBERT A. FALCONER